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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,733	ESCARY, JEAN-LOUIS	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented Claim 39 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed product requires nucleic acids, polypeptides, or a combination of both. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 39, drawn to isolated polynucleotides (some of which contain SNPs), classified in class 536, subclass 23.1.

II. Claims 21-24, and 26, drawn to methods for detecting an interferon alpha-14 nucleic acid sequence that is associated with a disease or resistance thereto, classified in class 435, subclass 6.

III. Claim 25, drawn to methods for determining statistically relevant associations between a disease and disease resistance and a SNP, classified in class 435, subclass 6.

IV. Claims 27-32 and 39, drawn to isolated polypeptides, classified in class 530, subclass 350 and 514..

V. Claim 33, drawn to antibodies, classified in class 530, subclass 387.1.

VI. Claims 34-36, drawn to a method for treating or preventing a disease by administering a polypeptide, classified in class 514, subclass 2.

VII. Claims 37-38, drawn to a method for identifying a compound with an activity similar to interferon alpha-14, classified in class 435, subclass 4 or 7.1.

3. Inventions I and II, and I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention I are nucleic acid molecules (some of which contain SNPs). The product as claimed by Invention I can be used in a materially different process such as synthesizing primers and probes or used in antisense therapy.

Inventions I and IV are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas Invention IV is drawn to polypeptides. Nucleic acids are composed of nucleotides and polypeptides are composed of amino acids. Accordingly, these compounds are independent and distinct from one another due to their diverse chemical structure, their expected different chemical properties, modes of action, different effects and reactive conditions.

Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of Invention IV do not requires the particular products of the nucleic acids of Invention I since the proteins of Invention IV can be isolated from natural sources or chemically synthesized.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of being used together. Furthermore, the nucleic acids of Invention I, which are composed of nucleotides, are chemically and biologically distinct from the antibodies of Invention V, which are composed of amino acids and have distinct structural and immunological properties.

Inventions I and VI, and I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Invention I are not disclosed as being used in the method of treating or preventing a disease in Invention VI or the method of identifying a compound with an activity similar to interferon alpha-14 in Invention VII.

Inventions II and III, II and VI, and II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

§ 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention II requires the use of an isolated nucleic acid used to detect an interferon alpha-14 nucleic acid sequence. The method of Invention III the genotyping of a individuals sample in order to determine statistically relevant association between a disease and a SNP. The method of Invention VI requires the administration of a polypeptide to treat or prevent a disorder linked to interferon alpha-14. The method of Invention VII requires determining the activity of a compound and comparing that with activity of a interferon alpha-14 protein in order to identify compounds with similar activity to interferon alpha-14 proteins.

Inventions II and IV and II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting an interferon alpha-14 nucleic acid sequence does not require the polypeptides of Invention IV or the antibodies of Invention V.

Inventions III and VI, and III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention III the genotyping of a individuals sample in order to determine

statistically relevant association between a disease and a SNP. The method of Invention II requires the administration of a polypeptide to treat or prevent a disorder linked to interferon alpha-14. The method of Invention VII requires determining the activity of a compound and comparing that with activity of a interferon alpha-14 protein in order to identify compounds with similar activity to interferon alpha-14 proteins.

Inventions III and IV and III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of determining statistically relevant associations between a disease or disease resistance and a SNP of Invention III does not require the polypeptides of Invention IV or the antibodies of Invention V.

Inventions IV and V are patentably distinct in structural and functional properties. Invention IV is drawn to polypeptides, while Invention V is drawn to antibodies. Although both proteins and antibodies are composed of amino acids, the antibodies of Invention V have distinct structural limitations not required of the polypeptides of Invention IV. Furthermore, antibodies have particular immunological functions that distinguish them from other polypeptides.

Inventions IV and VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the

polypeptides of Invention IV can be used in a material different process such as assays for protein purification.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention IV are not required in the method of method of identifying a compound with an activity substantially similar to an activity of an interferon alpha-14 protein.

Inventions V and VI, and V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention V are not required in the method of treating or preventing a disease or disorder linked to interferon alpha-14 or the method of identifying a compound with an activity substantially similar to an activity of an interferon alpha-14 protein.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention VI requires the administration of a polypeptide to treat or prevent a disorder linked to interferon alpha-14. The method of Invention VII requires determining the activity of a

compound and comparing that with activity of a interferon alpha-14 protein in order to identify compounds with similar activity to interferon alpha-14 proteins.

SNP Election Requirement Applicable to All Inventions

4. In addition, each Invention detailed above reads on a patentably distinct single nucleotide polymorphism (SNP) (i.e. g1318a or c1423t). Each SNP causes one nitrogenous base to be substituted for another at its location. The polymorphism may or may not have any affect on the amino acid sequence, however if it does it could encode for a protein having a different biological activity. Therefore each SNP is chemically, structurally and functionally distinct from all other SNPs. A search for one SNP would not be co-extensive with a search for another SNP. Further, a finding that a SNP, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that another SNP is also novel and unobvious over the prior art.

Accordingly, each SNP is deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, should the applicant elect an invention drawn to SNPs, the applicant must further elect a single SNP.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as exemplified by their different classification, restriction for examination

purposes as indicated is proper. Further, a search for Inventions I-VII would not be co-extensive because a search indicating that one method (i.e. detecting interferon alpha-14 nucleic acid sequences) is novel or nonobious would not extend to a holding that the other methods (i.e. determining statistically relevant associations between diseases and SNPs, treating diseases by administering a peptide, and identifying compounds with activitiy similar to interferon alpha-14) are also novel or nonobvious. This holds true for the products as well. A search indicating that one product (i.e. polynucleotides) is novel or nonobious would not extend to a holding that the other products (i.e. polypeptides and antibodies) are also novel or nonobvious. Similarly, a search indicating that these methods or products are known or would have been obvious would not extend to a holding that these methods or products are known or would have been obvious.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
February 22, 2006

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER